

Medtronic



Micra™ leadless pacemakers

The leader in leadless

Micra™ VR2

The world's smallest pacemaker¹

Micra™ AV2

Available with smarter
automatic AV synchrony²

Introducing the next generation of Micra leadless pacemakers

Micra AV2 and Micra VR2

Extended longevity

- Micra AV2 has a projected median longevity of 15.6 years – which is 44% more than its predecessor, Micra™ AV.³
- Micra VR2 has a projected median longevity of 16.7 years – which is 36% more than its predecessor, Micra™ VR.³
- This increased battery life means that more than 80% of patients are projected to need one Micra device for life.³ These innovations required zero change to the device size.

Smarter algorithms

- The enhanced Micra AV2 algorithms boast improvements to performance and efficiency by automatically customizing AV synchrony settings for each patient.²
- These automatic adjustments reduce the need for manual programming by more than 50% compared to its predecessor, Micra AV.²
- The smarter algorithm also improves automatic AV synchrony at faster heart rates between 80-100 bpm,² and the upper tracking rate limit is now 135 bpm.

Enhanced delivery system

- The delivery system now has a rounded catheter edge with more surface area to decrease tip pressure during device implant.⁴
- Micra AV2 and Micra VR2 devices are implanted with the same streamlined procedure as previous Micra devices.

10+ years

of leadless pacing
leadership⁵

40,000+

patients followed in
research activities⁵

10,000+

physicians trained⁵

300,000+

patients implanted
worldwide⁵

Unmatched leadless pacing experience

Revolutionized patient experience

- No chest scar
- No bump
- No visible or physical reminder of a pacemaker under the skin
- Fewer post-implant activity restrictions

Eliminated pocket-related complications⁶

- Infection
- Hematoma
- Erosion

Eliminated lead-related complications⁶

- Fractures
- Insulation breaches
- Venous thrombosis and obstruction
- Tricuspid regurgitation

Remote monitoring and capture management

- Micra leadless pacemakers are the only leadless pacemakers with both remote monitoring and capture management.
- App-based remote monitoring is also available on smartphones or tablets with MyCareLink Smart™ app.

Together,
we can provide new
opportunities to revolutionize
the patient experience
and reduce complications
associated with traditional
pacing technology.⁷⁻⁹

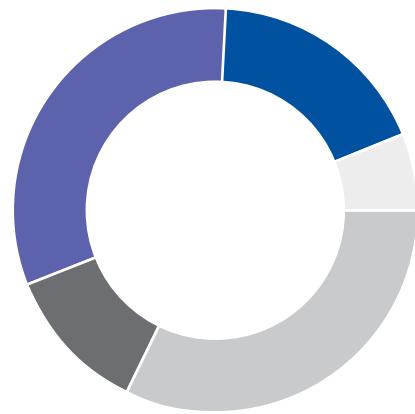
93%
smaller than
conventional
pacemakers¹



Unmatched leadless pacing experience

Micra leadless pacemakers are the world's smallest pacemakers for bradyarrhythmia management.¹

Micra AV2 provides improved automatic AV synchrony,² allowing more of your patients to benefit from leadless pacing.



- AVB only[†]
Potential Micra AV2 candidates¹⁰
- AVB + AF
Micra VR2¹⁰
- SND + AVB
- SND only
- Other

Pacing capsule technical specifications

Parameter	Micra AV2	Micra VR2
Pacing mode	VVI, VVIR, VOO, OVO, VDD, VDI, ODO, OFF	VVI, VVIR, VOO, OVO, OFF
Mass	1.75 g	1.75 g
Volume	0.8 cc	0.8 cc
Electrode spacing	18 mm	18 mm
Median projected battery longevity	15.6 years ³	16.7 years ³
Programmer	CareLink SmartSync™ device manager	CareLink SmartSync device manager
Accelerometer-based mechanical atrial sensing	✓	N/A
Accelerometer-based rate response	✓	✓
MRI SureScan™	≤ 3 T	≤ 3 T
Capture Management™	✓	✓
FlexFix™ nitinol tines	✓	✓
CareLink™ remote monitoring	✓	✓

[†] AVB-only patients who would benefit from leadless pacing per the indications for use.

- Anode

- Bipolar pacing



- Cathode

- Steroid-eluting electrode
- Separated from FlexFix tines to ensure optimal contact with myocardium



- Proximal retrieval feature

- Micra can be snared and retrieved using commercially available tools, if preferred

FlexFix nitinol tines

- Multidimensional redundancy:

Two tines have 15 times the holding force necessary to hold the device in place¹¹

- Designed to minimize tissue trauma during deployment, repositioning, and retrieval¹²

- Optimal electrode tissue interface allows for low and stable chronic thresholds¹³

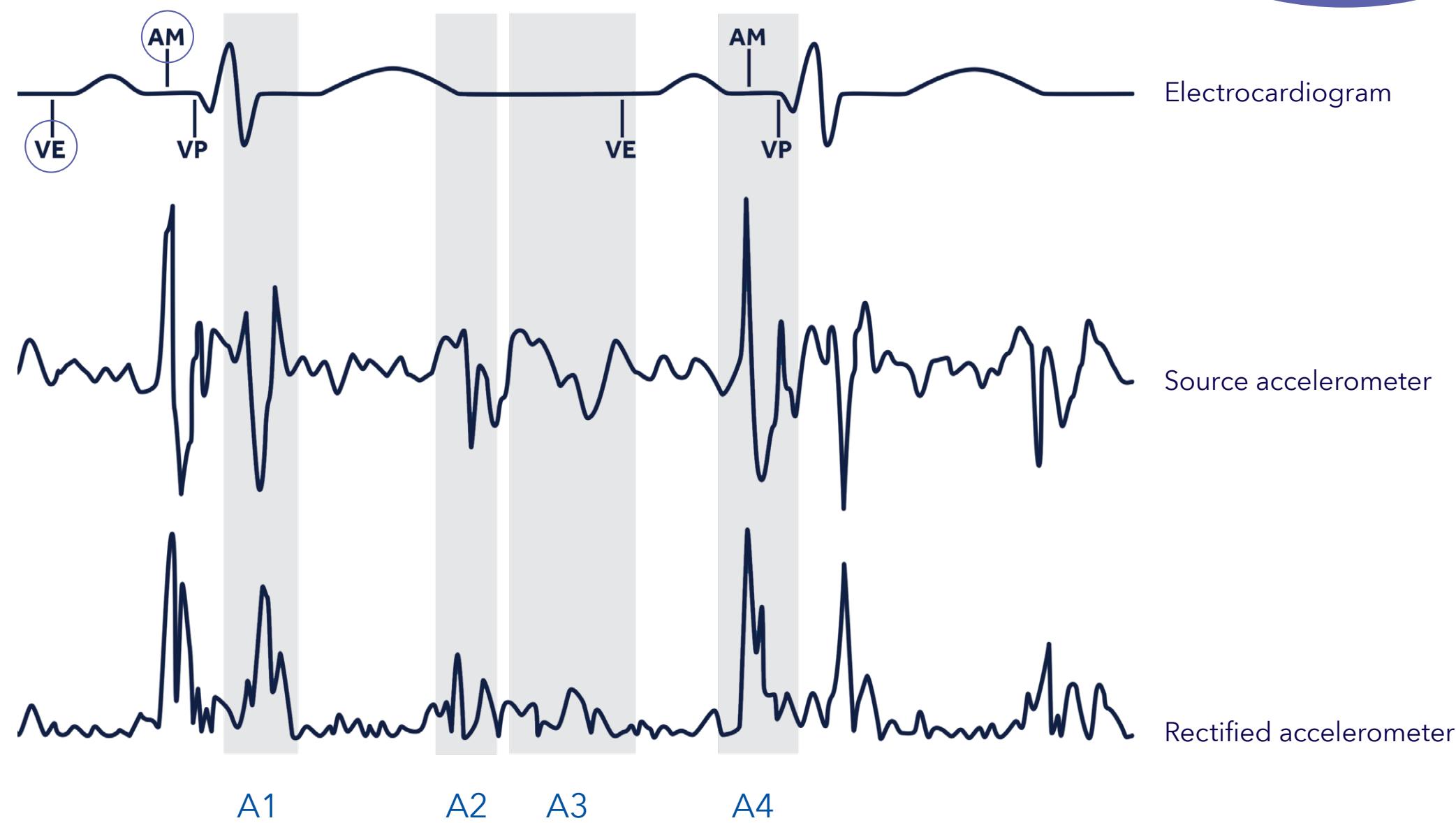


AV synchrony reimagined

The world's smallest pacemaker¹

Available with smarter automatic AV synchrony²

- The Micra AV2 accelerometer detects mechanical atrial activity and uses this information to deliver AV synchronous ventricular pacing.
- Delivers a median projected longevity of 15.6 years³



Ventricular end (VE) marker

Pacemaker timing indication of A3 window end should fall at the end of the A1-A3 ventricular event signals.

Atrial mechanical (AM) marker

Marker that indicates the device detected the atrial mechanical contraction or A4.

A1

Start of ventricular systole, mitral, and tricuspid valves close

A2

End of ventricular systole, aortic, and pulmonic valves close

A3

Diastole, passive blood flow from A to V, corresponds to E-wave on Doppler echo

A4

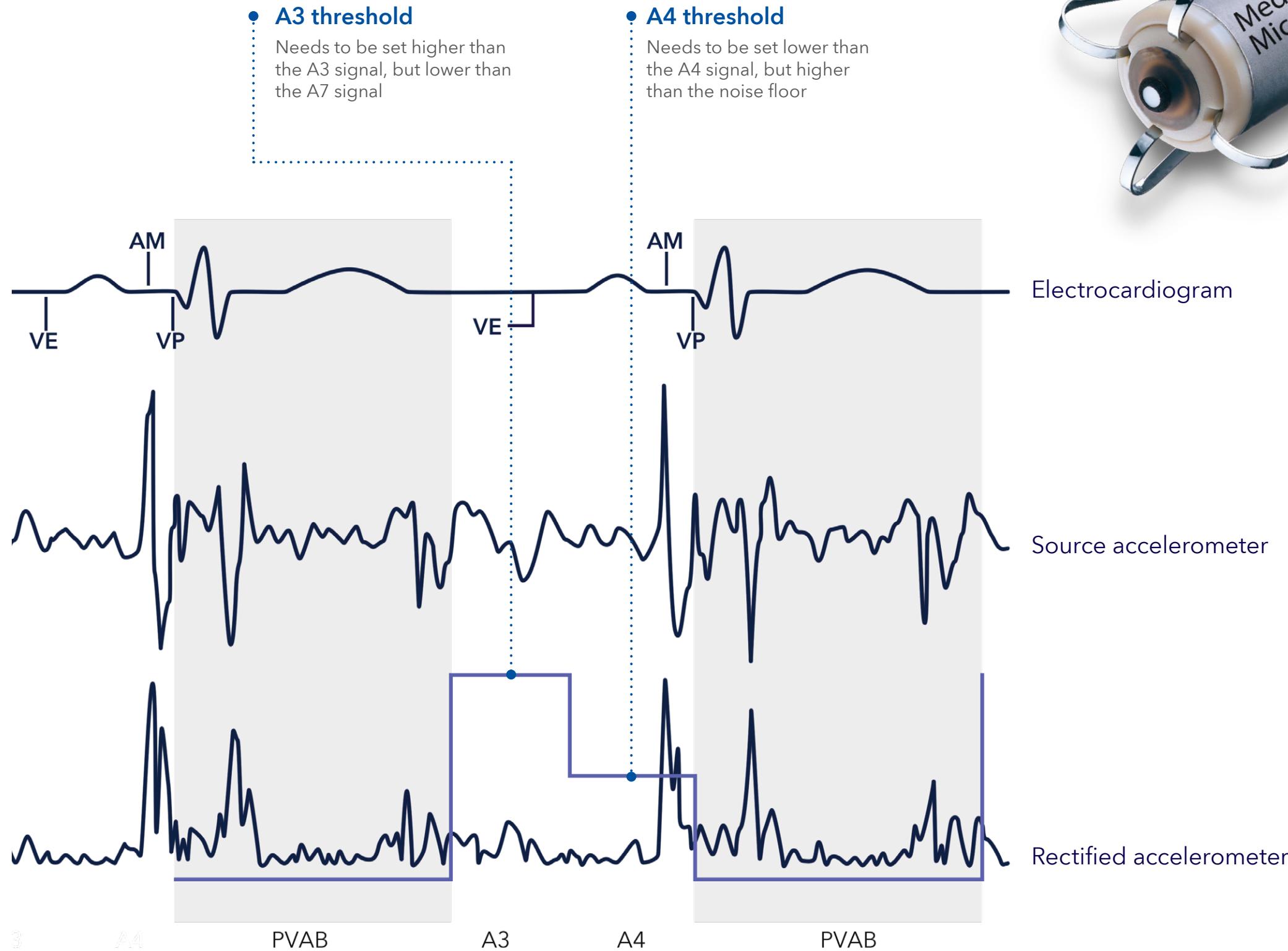
Atrial systole, blood pushed into ventricles, 100 ms electromechanical delay, corresponds to A-wave on Doppler echo

A7

Occurs when the A3 and A4 signals fuse at higher sinus rates: passive and active filling of the ventricles occurs simultaneously, resulting in a larger amplitude signal

AV synchrony reimagined

Micra AV2 accelerometer signals explained



Post-ventricular atrial blanking (PVAB) period

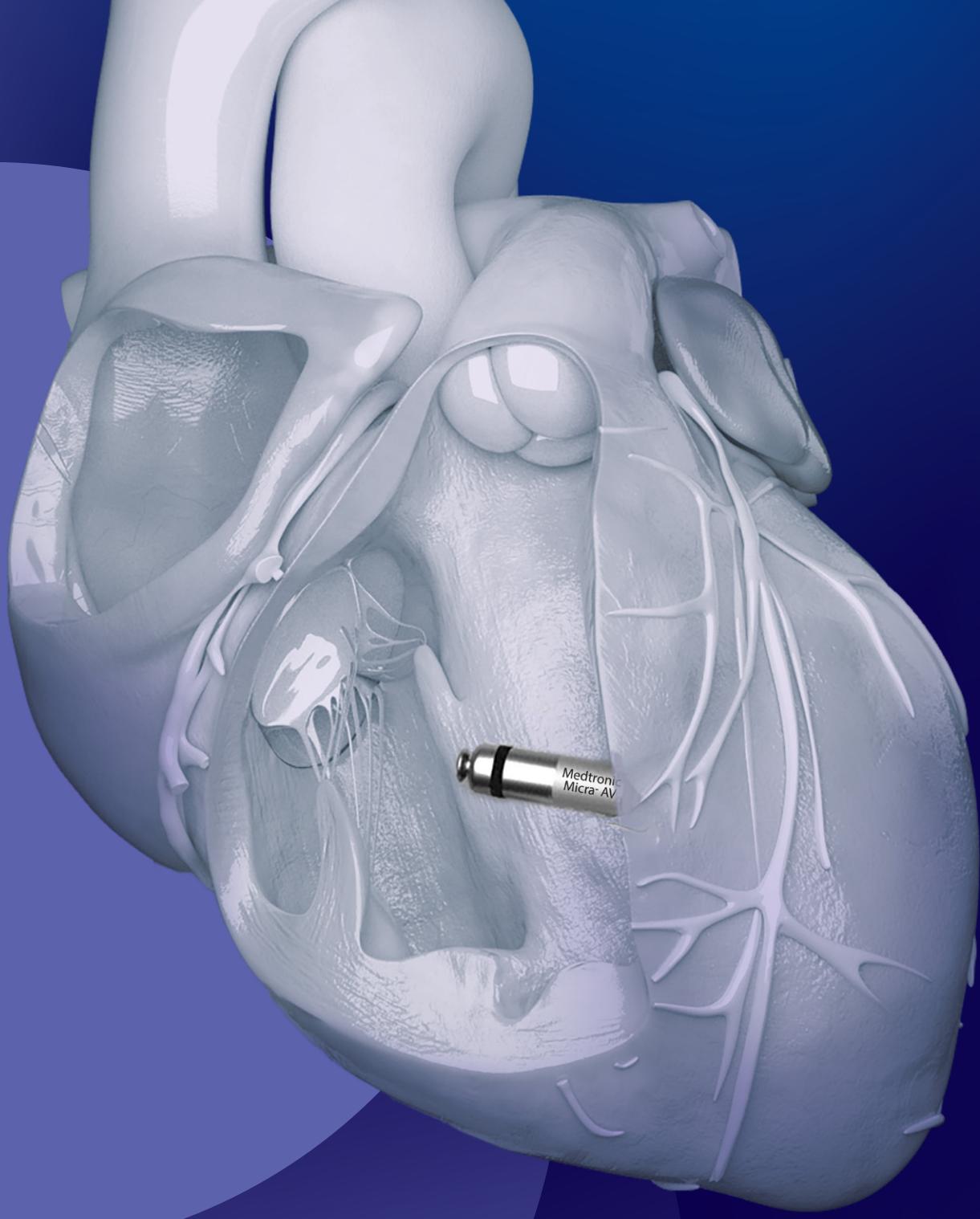
The A1 and A2 signals are blanked. No atrial sensing occurs during PVAB.

A3 detection window

A less-sensitive setting where only large accelerometer signals will trigger a detection. It is designed to avoid detecting the A3 signal while still detecting the A7 signal.

A4 detection window

Used to detect the A4 signal after ventricular diastole has completed



AV synchrony algorithms

Learn what's new with Micra AV2.

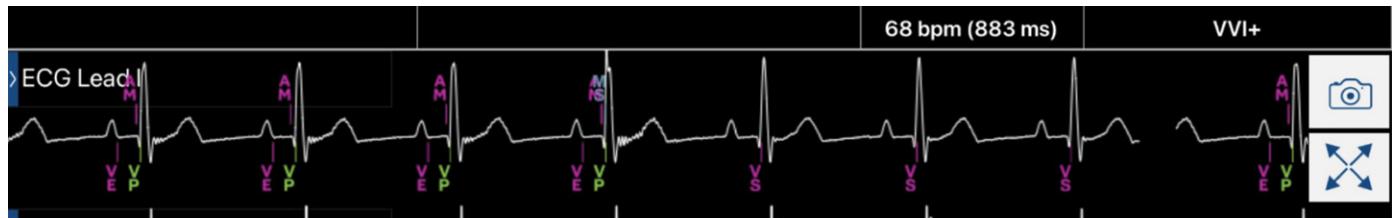
AV Conduction Mode switch

Micra AV2 will mode switch to VVI+ during periods of intact AV conduction to promote intrinsic rhythm in patients with episodic AV block.

- Designed to limit amount of RV pacing and maximize device longevity by disabling atrial sensing during mode switch
- Works by periodically dropping into VVI+ at AV Conduction Mode Switch Lower Rate and switches back to VDD when device paces

Micra AV2 provides a programmable AV Conduction Mode Switch Lower Rate versus fixed 40 bpm in Micra AV.

- Provides more flexibility to leave mode switch on for patients who have idioventricular rates > 40 bpm or high sinus rates with 2:1 block



Atrial Sensing Setup

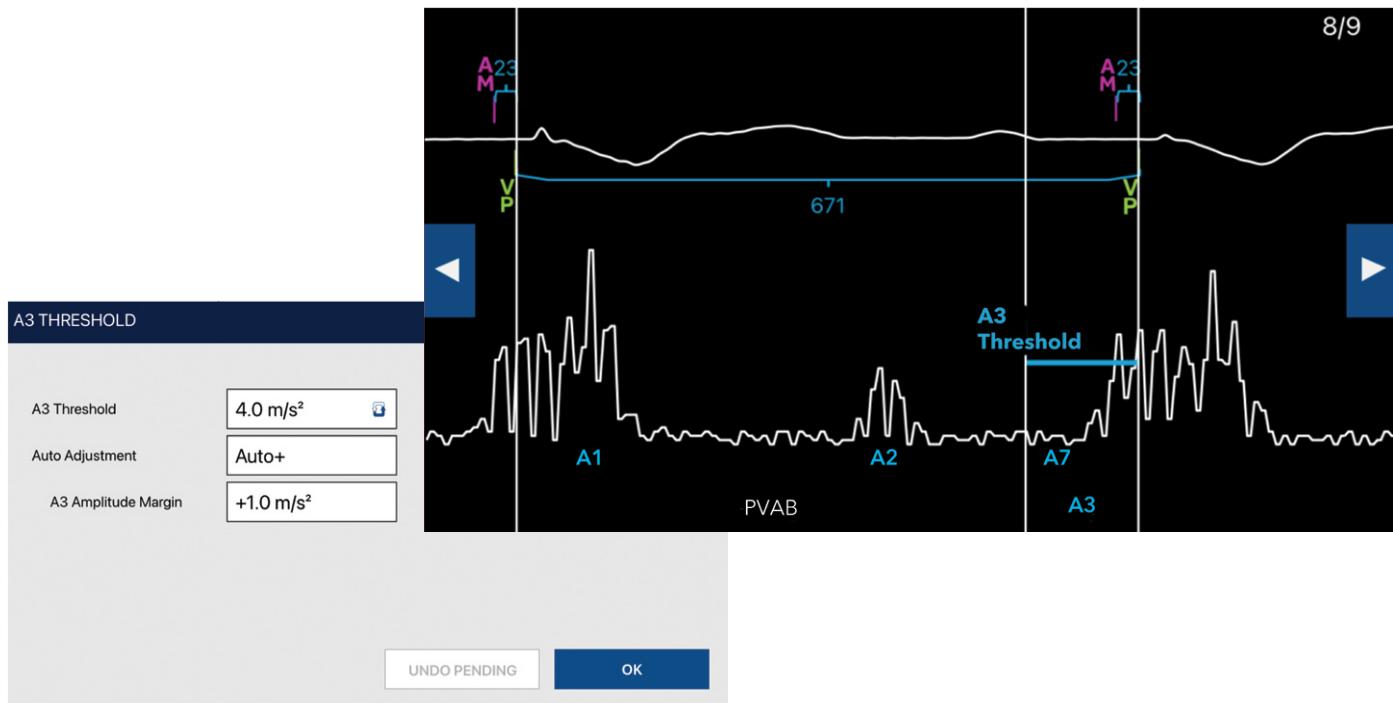
Micra AV2 will automatically set up AV synchrony parameters Atrial Sensing Vector, A3 and A4 Threshold, and A3 Window End related parameters after implant.

- Collects A3 and A4 signal data in VDI mode and then refines settings in VDI and VDD modes. Micra AV2 filters the A3 and A4 signal data for a more accurate method of setting these parameters.²
- Reduces need for manual programming by > 50% post-Atrial Sensing Setup and may contribute to a time savings of 13 minutes per post-implant device check.²

Auto+ A3 Threshold

Micra AV2 offers a new algorithm, Auto+, to automatically adjust the A3 Threshold.

- Auto+ uses filtered, true A3 signal amplitudes to automatically set the A3 Threshold above the A3 signal but below the A7 signal (summed A3 + A4 signal).
- Sensing of the A7 signal allows tracking at higher heart rates (> 85 bpm).
- Auto+ automatically provides better AV synchrony in the range of 80-100 bpm when directly compared to Auto A3 Threshold.²



Auto PVAB and Upper Tracking Rate

Micra AV2 offers an Auto PVAB algorithm which adjusts PVAB based on ventricular rate.

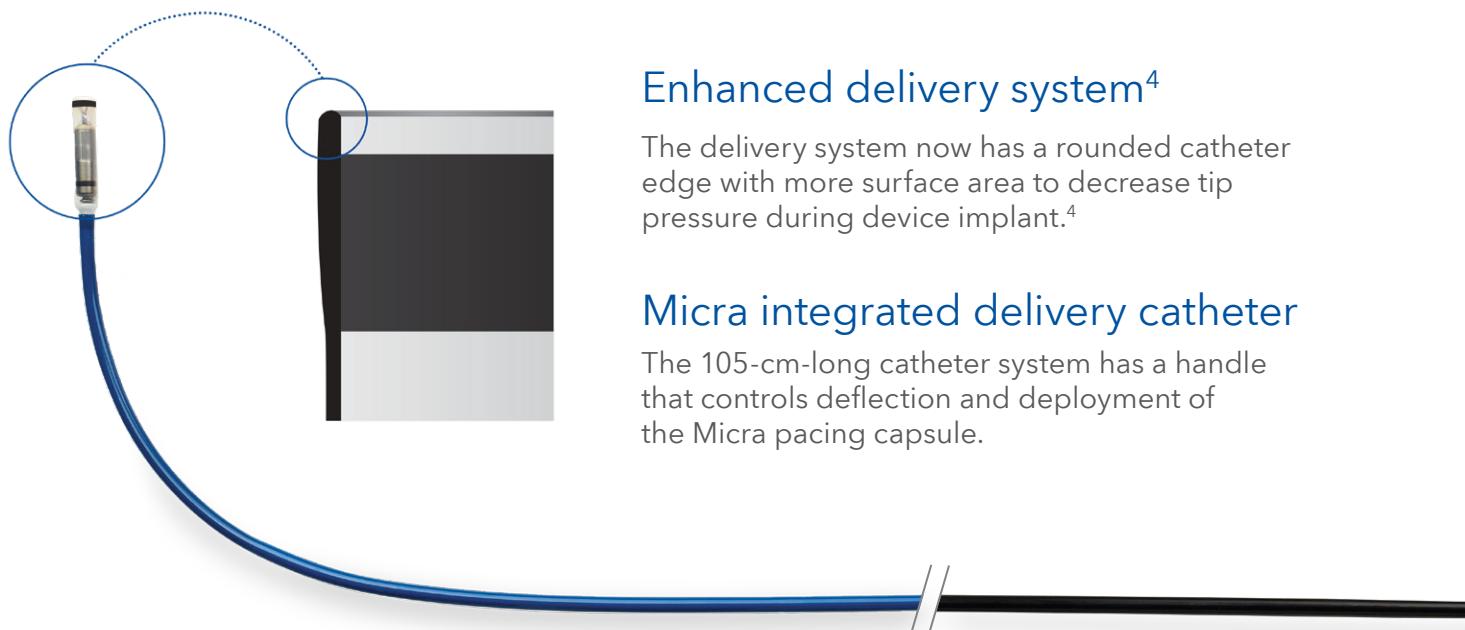
- When set to Auto, the device switches from the Max PVAB to Min PVAB setting at the PVAB Switch Rate, allowing for a dynamic PVAB.
- To benefit patients who are active, Micra AV2 has a higher available tracking capability for faster heart rates.² The shortest Min PVAB setting of 425 ms and expanded Upper Tracking Rate settings allow tracking up to 135 bpm, compared to 115 bpm on the previous generation Micra AV.

atrial parameters			
Sensed AV (AM-VP)	20 ms	Rate Smoothing	On
PVAB	Auto	Smoothing Delta	100 ms
PVAB Switch Rate	90 bpm (665 ms)	Tracking Check	Off
Min PVAB	500 ms	Atrial Sensing Setup	Off/Complete
Max PVAB	550 ms		
PVARP	Auto		
Max PVARP	600 ms	UNDO PENDING	OK



Same streamlined procedure

with an enhanced delivery system⁴

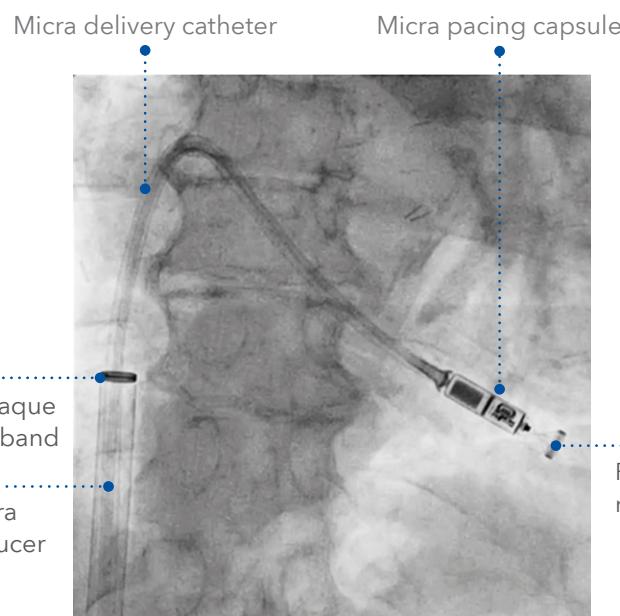


Enhanced delivery system⁴

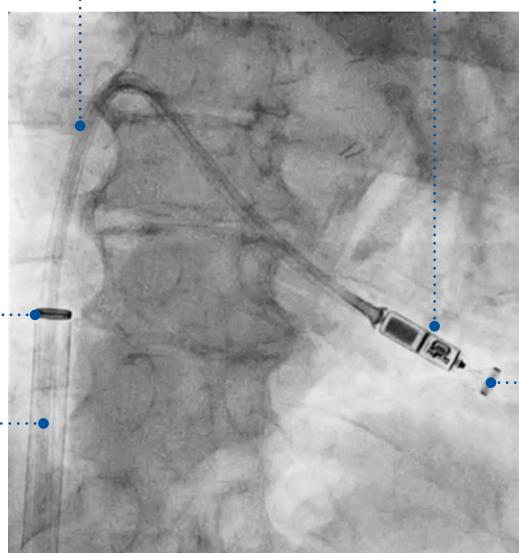
The delivery system now has a rounded catheter edge with more surface area to decrease tip pressure during device implant.⁴

Micra integrated delivery catheter

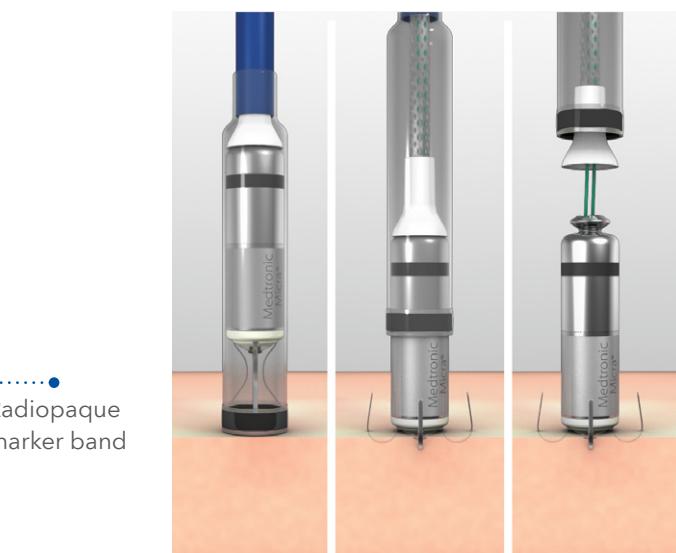
The 105-cm-long catheter system has a handle that controls deflection and deployment of the Micra pacing capsule.



Radiopaque
marker band
Micra
introducer

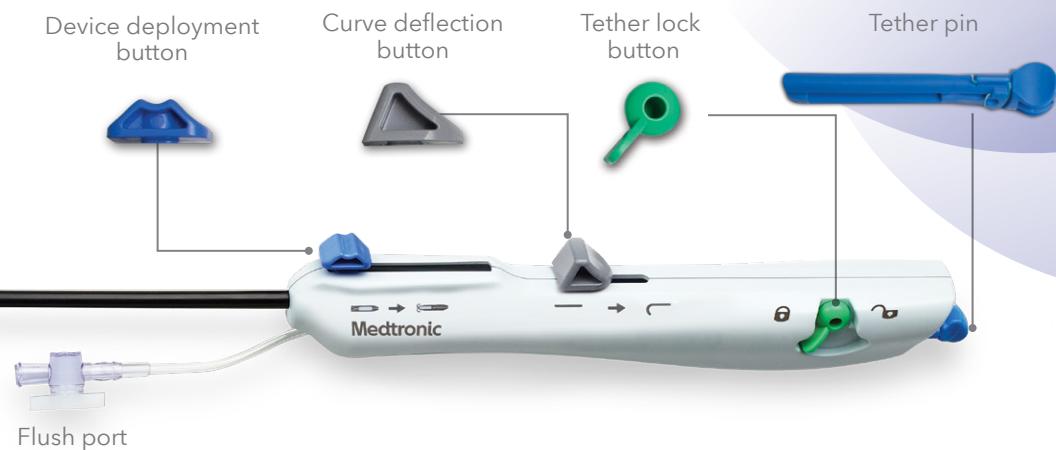


Delivery catheter provides visual feedback when adequate tip pressure has been achieved, and retracts during deployment.



Linear one-step deployment facilitates consistent capsule placement; no torque required.¹¹

>99%
implant success in
Micra VR clinical studies^{14,15}



Smooth vessel navigation with the Micra introducer

- Lubricious hydrophilic coating
- 23 Fr inner diameter (27 Fr outer diameter)
- Silicone oil-coated dilator tip

Alternative access options

All Micra leadless pacemakers are approved for jugular access.

Device life cycle management options

Micra is designed to offer options at the end of service.

- Micra, designed as the world's smallest pacemaker,¹ can be left in place at end of service because of its small size. When programmed OFF, it can be differentiated from subsequent devices.
- Micra, also designed with a proximal retrieval feature, can be removed when preferred. Successful retrieval has been demonstrated at nine years with commercially available tools.¹⁶

The promise of leadless pacing has been realized through five years.⁸

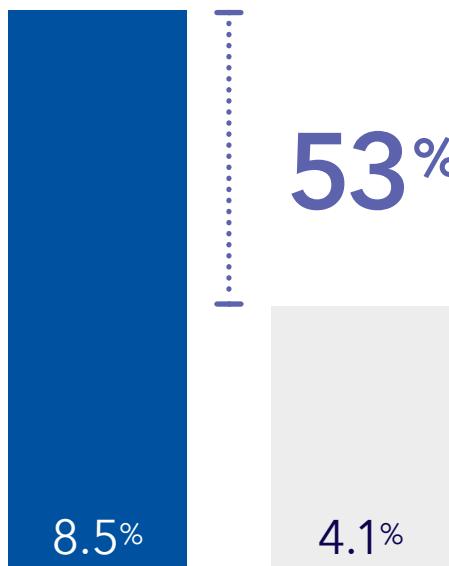
Micra™ VR real-world evidence

Micra VR PAR⁸

3- and 5-year results

Prospective, nonrandomized, real-world registry of Micra VR patients with adjunction of system- and procedure-related events by an independent clinical events committee (with historical comparator cohort).

Major complications (3 year)



Results sustained through five years:

- 0** Infections requiring device removal
- 2.0%** Rate of CRT device upgrade
- 4.5%** Rate of major complications
- 4.9%** Rate of system revisions

Significant reduction in complications compared to transvenous pacemakers.^{8,9}

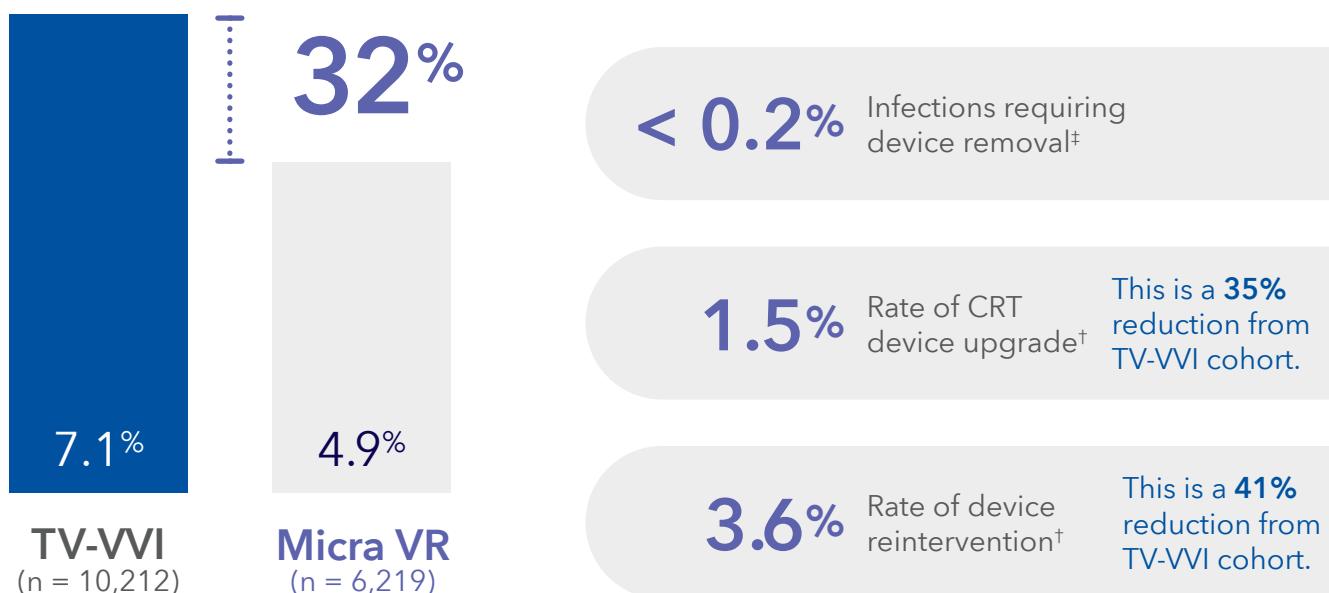
Zero infections requiring device removal through five years.⁸

Low rate of CRT upgrades in both the PAR and CED.^{8,9}

Micra VR CED⁹ **3-year results**

Administrative claims-based study of the Medicare beneficiaries implanted with Micra VR (with contemporaneous comparator cohort).

Chronic complications[†] (3 year)



[†] Rates adjusted for differences in patient baseline characteristics.

[‡] CMS suppression requirement for values < 11.

Reduced complications with the world's smallest pacemaker for AV block.^{1,17,18}

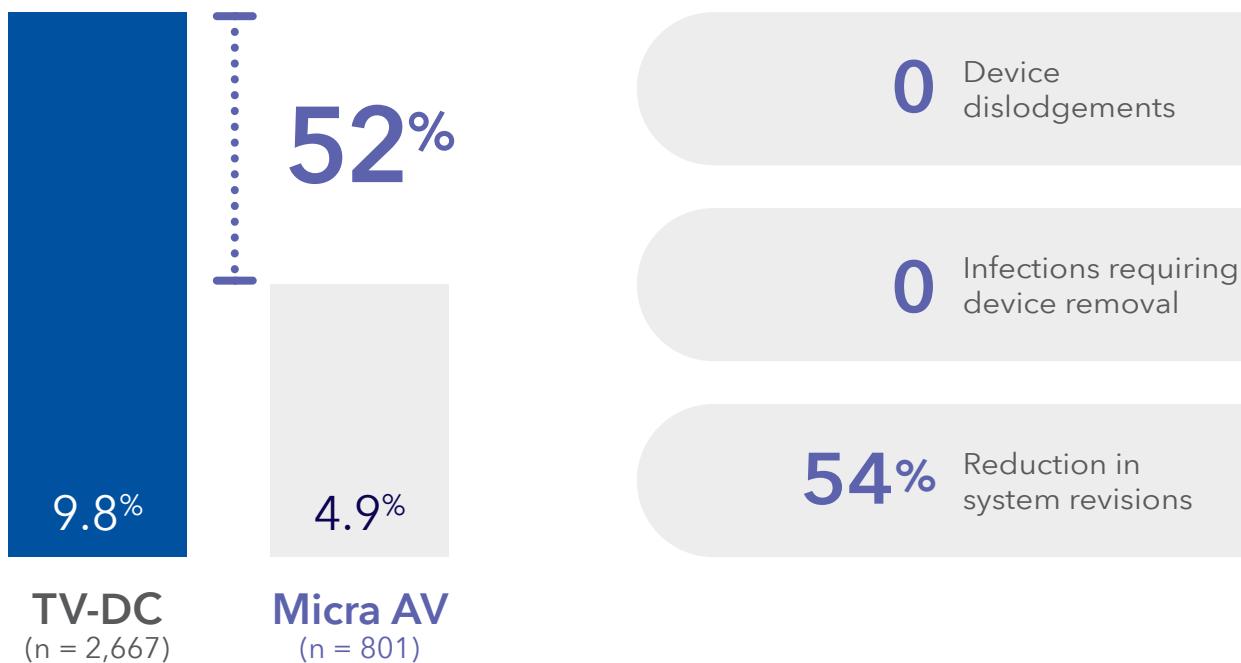
Micra™ AV real-world evidence

Micra AV PAR¹⁷

3-year results (interim analysis)

Prospective, nonrandomized, real-world registry of Micra AV patients with adjudication of system- and procedure-related events by an independent clinical events committee (with historical comparator cohort).

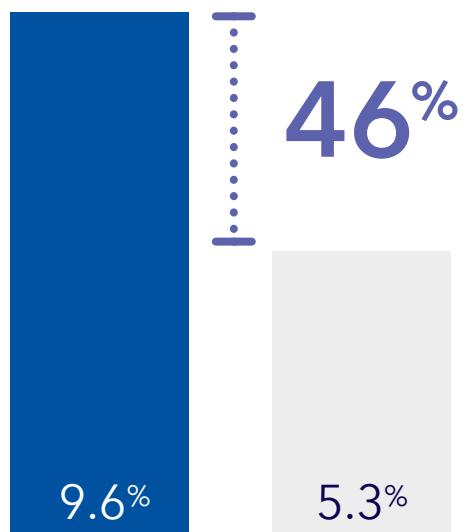
Major complications (3 year)



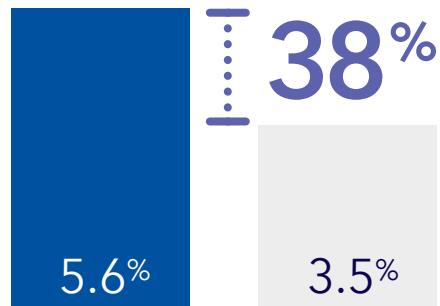
Micra AV CED¹⁸ 2-year results

Administrative claims-based study of Medicare beneficiaries implanted with Micra AV (with contemporaneous comparator cohort).

Chronic complications[†] (2 year)



Reinterventions[†] (2 year)



1.6%
Rate of CRT
upgrades[†]

[†] Rates adjusted for differences in patient baseline characteristics.

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Brief Statement

Micra, Micra AV, Micra VR2, and Micra AV2

Indications: Micra Model MC1VR01, Micra VR2 Model MC2VR01, and Micra AV Model MC1AVR1, are indicated for use in patients who have experienced one or more of the following conditions:

- Paroxysmal or permanent high-grade AV block in the presence of AF
- Paroxysmal or permanent high-grade AV block in the absence of AF, as an alternative to dual chamber pacing, when a dual-chamber transvenous pacing system is considered difficult, high risk, or not deemed necessary for effective therapy
- Symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses), as an alternative to atrial or dual chamber pacing, when a dual-chamber transvenous pacing system is considered difficult, high risk, or not deemed necessary for effective therapy

Micra AV Model MC1AVR1 is also indicated for VDD pacing in patients with adequate sinus rates who may benefit from maintenance of AV synchrony. The Micra AV device provides AV synchronous ventricular pacing similar to a transvenous VDD system. The implanted device depends on the appropriate sensing of atrial mechanical signals to achieve AV synchrony. The level of AV synchrony may vary in individual patients and may not be predictable prior to implant.

For MC1VR01 and MC2VR01, rate-responsive pacing is indicated to provide increased heart rate appropriate to increasing levels of activity.

The device is designed to be used only in the right ventricle.

Micra AV2 Model MC2AVR1 is indicated for VDD pacing in patients when a dual chamber transvenous pacing system is considered a poor option or not deemed necessary for effective therapy, and when a right ventricular transcatheter pacing system promoting AV synchrony at rest is acceptable. Conditions when a patient is considered a poor candidate for transvenous pacing may include, but are not limited to, tortuous anatomy, a need to preserve venous access, or increased risk of infection. The device provides AV synchrony at rest and rate responsive (VVI) pacing during periods of high patient activity.

Device-mediated AV synchrony can vary depending on patient condition and activity levels, and it can be limited at high sinus rates. During periods of intermittent AV synchrony, the device will provide ventricular pacing support with an increased potential for pacing rate variability. Micra AV2 is indicated for use in patients who have experienced one of the following:

- Paroxysmal or permanent high-grade AV block in the absence of AF
- Paroxysmal or permanent high-grade AV block in the presence of paroxysmal AF
- Paroxysmal or permanent high-grade AV block in the presence of persistent AF when attempts at restoring sinus rhythm are still planned

The device is designed to be used only in the right ventricle.

Contraindications: Micra Model MC1VR01, Micra AV Model MC1AVR1, Micra VR2 Model MC2VR01 and Micra AV2 Model MC2AVR1 are contraindicated for patients who have the following types of medical devices implanted: an implanted device that would interfere with the implant of the Micra device in the judgment of the implanting physician, an implanted inferior vena cava filter is present and jugular venous anatomy unable to accommodate a 7.8 mm (23 Fr) introducer sheath or implant on the right side of the heart (for example, due to obstructions or severe tortuosity), a mechanical tricuspid valve, or an implanted cardiac device providing active cardiac therapy that may interfere with the sensing performance of the Micra device.

The device is contraindicated for patients who have the following conditions: venous anatomy is unable to accommodate a 7.8 mm (23 Fr) introducer sheath or implant on the right side of the heart (for example, due to obstructions or severe tortuosity), morbid obesity that prevents the implanted device from obtaining telemetry communication within ≤ 12.5 cm (4.9 in), or known intolerance to the materials listed in the Instruction for Use, or to heparin, or sensitivity to contrast media that cannot be adequately premedicated, or if the steroid dose from this device cannot be tolerated.

Warnings and Precautions: End of Service (EOS) - When the EOS condition is met, the clinician has the option of permanently programming the device to Off and leaving it in the heart, or retrieving the device, provided the device has not yet become encapsulated. Removal of the Micra device after it has become encapsulated may be difficult because of the development of fibrotic tissue. If removal of the device is required, it is recommended that the removal be performed by a clinician who has expertise in the removal of implanted leads.

MRI conditions for use - Before an MRI scan is performed on a patient implanted with the Micra

device, the cardiology and radiology professionals involved in this procedure must understand the requirements specific to their tasks as defined in the device manuals.

Rate-responsive mode may not be appropriate for patients who cannot tolerate pacing rates above the programmed Lower Rate. The patient's age and medical condition should be considered by physicians and patients as they select the pacing system, mode of operation, and implant technique best suited to the individual.

Precautions should be taken before administering anticoagulant agents, antiplatelet agents, or contrast media in patients with known hypersensitivity to these agents.

The use of deactivated Micra devices in situ and an active Micra device, or an active transvenous pacemaker or defibrillator, has not been clinically tested to determine whether EMI or physical interaction is clinically significant. Bench testing supports that implantation of an active Micra device, or an active transvenous pacemaker or defibrillator, next to an inactivated Micra device is unlikely to cause EMI or physical interaction. Post-approval studies are planned to characterize risks of co-implanted, deactivated Micra devices. Currently recommended end of device life care for a Micra device may include the addition of a replacement device with or without explanation of the Micra device, which should be turned off.

For Micra AV Model MC1AVR1 and Micra AV2 Model MC2AVR1, patient activities and environments which present mechanical vibrations to the patient can interfere with the mechanical sensing of atrial contractions. This can result in a loss of AV synchrony.

Potential Adverse Events

Potential complications include, but are not limited to, toxic/allergic reaction, oversensing, pacemaker syndrome, cardiac arrest, acceleration of tachycardia, necrosis, myocardial infarction and surgical complications such as cardiac perforation, pericardial effusion, cardiac tamponade, device embolization, hematoma, AV fistula, vessel dissection, infection, cardiac inflammation, and thrombosis, air embolism, heart block, seroma, and tissue trauma.

See the device manuals for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, MRI conditions for use, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult Medtronic's website at www.medtronic.com.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Medtronic CareLink™, MyCareLink™, MyCareLink Smart™ Patient Monitors, MyCareLink Smart™ Application, Medtronic CareLink™ Network, CareLink™ Mobile Application, and Medtronic MyCareLink Connect™ Patient Website

Indications: The Medtronic CareLink, MyCareLink, MyCareLink Smart Patient Monitors, MyCareLink Smart Application, CareLink Network and the CareLink Mobile Application are indicated for use in the transfer of patient data from some Medtronic implantable cardiac devices to the Medtronic CareLink Network based on physician instructions and as described in the product manual. Medtronic CareAlerts are not intended to be used as the sole basis for making decisions about patient medical care. These products are not a substitute for appropriate medical attention in the event of an emergency and should only be used as directed by a physician. The CareLink Mobile Application is intended to provide current CareLink Network customers access to CareLink Network data via a mobile device for their convenience. The CareLink Mobile Application is not replacing the full workstation, but can be used to review patient data when a physician does not have access to a workstation.

The CareLink Mobile Application and the MyCareLink Smart mobile application have minimum requirements for the mobile device and operating system. The minimum requirements for the mobile device and operating system are expected to change over time. Periodically, the patient may need to update their mobile device's operating system, or replace their mobile device to continue to use the app to transfer data to the CareLink Network. The MyCareLink Connect Patient Site is intended to provide patients, their friends/family and caregivers messages regarding transmission status of patient device diagnostic data to the CareLink Network. The MyCareLink Connect Patient Website is dependent on certain browser software, and that software is expected to change over time. Patients that are experiencing technical issues with the MyCareLink Connect Patient Website should contact Medtronic Patient Services at the number below. Data availability, alert notifications and patient messages are subject to Internet connectivity, access, and service availability. The CareLink and MyCareLink Patient Monitors and the MyCareLink Smart Reader must be on and in range of the device. The MyCareLink Smart Reader must also be within range of the patient's mobile device. The CareLink Network and mobile device accessibility to the CareLink Network may be unavailable at times due to maintenance or updates, or due to coverage being unavailable in your area. Mobile device access to the Internet is required for the CareLink Mobile App and the MyCareLink Smart Monitoring System and subject to coverage availability. Standard data and text message rates apply. Message frequency depends on account settings and clinic scheduling.

Contraindications: There are no known contraindications.

Warnings and Precautions: The CareLink, MyCareLink and MyCareLink Smart Patient Monitors must only be used for interrogating compatible Medtronic implantable devices. While using the CareLink or MyCareLink Patient Monitor, do not use a cellular phone while the antenna is positioned over the implanted device. The CareLink and MyCareLink Monitors are intended for use within the prescribing country. The MyCareLink Smart Patient Monitors may be used internationally. Standard mobile device availability and rates apply.

See the device manuals for detailed information regarding the instructions for use, indications or intended uses, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1 (800) 929-4043 and/or consult the Medtronic website at www.medtronic.com.

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